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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,959	03/03/2004	Hal H. Katz	END-5011USNP	5088
27777 7590 04/18/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT	PAPER NUMBER
			3763	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/791,959

Applicant(s)

KATZ ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-22 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/7/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the RCE filed 2/01/2007 in which claims 16 and 17 were amended. Currently claims 1-22 are pending for examination with claims 1-15 withdrawn.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 8/07/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Response to Arguments

Applicant's arguments with respect to claims 16-22 have been considered but are moot in view of the new ground(s) of rejection (see below).

Claim Objections

Claim 18 is objected to because of the following informalities: Regarding claims 18, the step of disconnecting the input signals from the at least one sensor from the at least one first connection point is unclear, how can the (electrical) input signals from the sensor be disconnecting from the first connection point(?) as currently claimed. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3763

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Bassuk et al. (6,723,086). Bassuk et al. discloses a remote controlled transdermal medication delivery device.

Regarding claims 16-17, Bassuk et al. discloses a medication delivery system comprising a plurality of different sensors (100) for monitoring a patients physiological parameter (col 7, ln 10-25), providing a first microprocessor based patient unit (36) having at least one connection point (34) through the wireless communication interface and receiving input signals from the at least one sensor (col 7, ln 25-40) and at least one second connection point (34) through the wireless connection interface for outputting patient physiological parameters to the physician through the physician station (32, col 4, ln 20-40) allowing for patient input into the system through display

(96) to adjust the medication levels and storing a patient record in a database (42) and connecting the at least one second connection point to a second microprocessor based unit (24) which is linked with a drug (68) in fluid communication and terminating the wireless second connection point (34) after physician intervention during the drug dosing (Figures 1-8).

Claim Rejections - 35 USC § 102

Claims 16-17 and 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Hickie (6,745,764). Hickie discloses an apparatus and method for providing a conscious patient relief from pain during surgical procedures.

Regarding claims 16-17 and 19-21, Hickie discloses a method for monitoring a patient comprising connecting to the patient a plurality of sensors (12a) for monitoring at least physiological parameter of a patient (col 10, ln 35-55) having at least connection point and receiving signals to a first microprocessor (14) based patient unit and at least one second connection point (connection points between the processors shown in Figure 4A) for outputting patient physiological parameters, creating a patient record through an interface (35) and remote (45) and printer (37), providing a drug delivery system (142) in fluid communication with the patient controlled by the second microprocessor (2a) through a second connection points from the primary controller (14) and upon termination of the medical procedure, removing the connection points to the patient and controllers (Figures 1-18). Hickie further discloses the step of providing oxygen to a patient (col 3 ln 50-70 and col 4, ln 1-15), querying a patient for a level of

consciousness (col 4, ln 45-55), and the step of the patient activating a response (305) device (col 9) (see summary of invention, Figures 1-23A).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18 and 22 are rejected under 35 U.S.C 103(a) as being unpatentable over Bassuk et al. or Hickie in view of Manica (5,679,245). Bassuk et al. or Hickie meet the claim limitations as described above except for the explicit disclosure of disconnecting the patient connection and priming an IV system tube.

However, Manica teaches a retention device for extracorporeal treatment.

Regarding claims 18 and 22, Manica teaches a step of priming an IV tube system (216) (col 14) and several steps of disconnecting several patient control pathways and connection points (236) (col 22-24, Figures 1-4).

At the time of the invention, in not inherent in the medical procedures to disconnect the connection points after a medical procedure it would have been obvious to add the steps of disconnecting the connection points and priming an IV based drug delivery system of Manica to the systems of Bassuk et al. or Hickie in order to ensure accurate drug delivery and protection against air embolism. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Manica.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3/22/07

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AU 3763

Alfred

U.S. DEPARTMENT OF COMMERCE
PATENT EXAMINER
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